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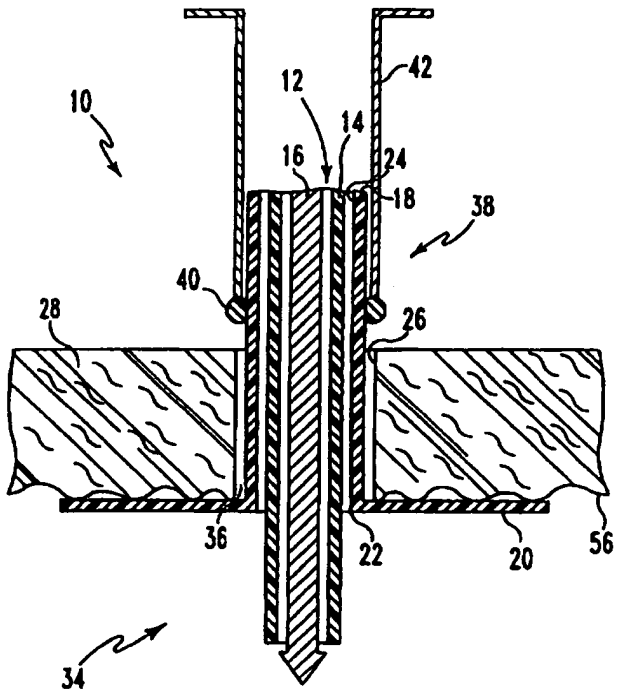
(57) Abstract

A medical apparatus includes a trocar assembly including a cannula and a trocar. The medical apparatus further includes a sleeve having a number of sealing members extending therefrom, and a passageway extending therethrough, with the trocar assembly being positioned within the passageway of the sleeve. The sleeve is positionable within an opening defined in a wall of a body cavity. Moreover, the sealing members are movable between (1) a first orientation in which the sealing members are positioned to facilitate advancement of the sleeve into the opening, and (2) a second orientation in which the sealing members are positioned to prevent fluid communication between an area inside of the body cavity and an area outside of the body cavity through a space defined between the opening of the body cavity and the sleeve. A medical procedure which uses the medical apparatus is also disclosed.



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APPARATUS AND METHOD FOR PROTECTING A PORT SITE OPENING IN THE WALL OF A BODY CAVITY

Background of the Invention

The present invention generally relates to an apparatus and method for protecting a port site opening in the wall of a body cavity. The present invention particularly relates to an apparatus and method for protecting a port site opening in the wall of a body cavity which is used with a trocar assembly.

Minimally invasive surgical techniques, such as laparoscopic surgery, typically include a trocar to create a small hole or port in a wall of a body cavity so as to gain access to the body cavity. Surgery performed by using these techniques is generally associated with lower postoperative morbidity, shorter postoperative stay, less postoperative pain, decreased cost, and quicker recovery as compared to "open" or conventional surgical techniques. Because of the aforementioned advantages, these minimally invasive techniques are being applied to an increasing variety of all surgical procedures. For example, laparoscopic procedures for the resection of malignancies have emerged. In particular, laparoscopic colectomy for carcinoma of the colon has been developed, and it has been reported that the initial results of these procedures have advantages over operations performed in the traditional open manner. Moreover, it is hoped that the long term results of these procedures will be comparable, or better than, those performed in the traditional open manner.

However, the field of laparoscopic surgery for cancer has been delayed in its development because of the major concern regarding the implantation of tumor cells in the port site wound. Minimally invasive surgical techniques for treating cancer require the removal of a malignant neoplasm through the small

incision or port site created by a trocar. These procedures require the dragging of tumor tissue through the port site which creates a risk of implanting tumor cells in the walls of the wound forming the extraction site. An additional concern is that tumor cells exfoliated during the procedure will come into contact with, and contaminate, the port site wound. This contamination can occur as a result of the exfoliated tumor cells being in fluid communication with the port site wound. Regardless of how these cells contaminate the wound, once implanted therein, viable tumor cells can cause a subcutaneous metastases or "port/extraction site recurrence" after the resection of malignant tissue. In fact, numerous port site recurrences have been documented in the medical literature heretofore; and subcutaneous metastases after laparoscopic resection of malignant tissue has been described as a potentially serious complication of laparoscopic cancer surgery. These "port/extraction site recurrences" have delayed the advancement of laparoscopic cancer surgery.

Furthermore, laparoscopic surgery performed for general surgery, gynecological surgery, urological surgery, or any other intra-abdominal infection is associated with a small but real incidence of port site wound infection. The infecting bacteria causing these illnesses can contaminate the port site wound by the same mechanism as discussed above with reference to tumor cell contamination, and these infections can increase a patients morbidity and consequently the length of a patient's hospital stay, thereby considerably increasing their hospital bill.

Therefore, in light of the above discussion, it is apparent that an apparatus for preventing port site tumor implantation and reducing the incidence of port site infection, is desirable. The present invention provides such an apparatus in the

form of a protective trocar sleeve. One advantage the present invention has over the prior art is that it can be retrofit to existing trocar assembly technology. Moreover, once attached, the described invention adds only a minimal amount of bulk to the diameter of the trocar assembly.

In use, the present invention protects the port site from infection or tumor cell implantation thereby lowering the morbidity and mortality of a wide variety of minimally invasive surgical techniques. The present invention allows the field of laparoscopic surgery to be safely applied to all forms of cancer surgery while minimizing "port site recurrences." The present invention also allows the field of laparoscopic surgery to be safely applied to all forms of laparoscopy while minimizing port site infections.

Summary of the Invention

In accordance with one embodiment of the present invention, there is provided a medical apparatus which includes a trocar assembly having a cannula and a trocar. The medical apparatus also includes a sleeve having a number of sealing members, and a passageway extending therethrough, with the trocar assembly positioned within the passageway of the sleeve.

Pursuant to another embodiment of the present invention, there is provided a medical apparatus, including a sleeve having a number of sealing members attached and a passageway extending therethrough. The medical apparatus also includes a cannula positioned within the passageway of the sleeve, with the cannula defining a lumen through which medical instruments may be advanced.

According to yet another embodiment of the present invention, there is provided an apparatus for use with a trocar assembly. The apparatus includes a sleeve having a number of sealing members, and a passageway extending therethrough, the sealing members being movable between (1) a first orientation in which the sealing members are positioned to facilitate advancement of said sleeve into an opening defined in a wall of a body cavity, and (2) a second orientation in which the sealing members are positioned to prevent fluid communication between an area inside of the body cavity and an area outside of the body cavity through a space defined between the opening in the wall of the body cavity and the sleeve. The apparatus further includes an actuator for moving the sealing members between the first orientation and the second orientation.

Pursuant to still another embodiment of the present invention, there is provided a medical procedure. The medical procedure includes the steps of creating an opening in a wall of a body cavity, and advancing a medical apparatus through the opening and into the body cavity, the medical apparatus including (1) a sleeve having a number of sealing members, and a passageway extending therethrough, and (2) a trocar assembly positioned within the passageway of the sleeve, the trocar assembly including a cannula and a trocar. The medical procedure further includes the step of positioning the sealing members to contact an interior surface of the body cavity.

It is therefore an object of the present invention to provide a new and useful medical apparatus.

It is another object of the present invention to provide an improved medical apparatus.

It is still another object of the present invention to provide a new and useful medical apparatus for protecting a port site wound from tumor cell implantation or contamination with an infectious agent.

It is another object of the present invention to provide an improved medical apparatus for protecting a port site wound from tumor cell implantation or contamination with an infectious agent.

It is moreover an object of the present invention to provide a new and useful medical procedure for performing minimally invasive surgery.

It is still another object of the present invention to provide an improved medical procedure for performing minimally invasive surgery.

It is also an object of the present invention to provide a medical apparatus for protecting a port site wound which can be retrofit to existing trocar assembly technology.

It is still another object of the present invention to provide a medical apparatus for protecting a port site wound which adds only a minimal amount of bulk to the diameter of a trocar assembly.

The above and other objects, features, and advantages of the present invention will become apparent from the following description and attached drawings.

Brief Description of the Drawings

FIG. 1 is a fragmentary side elevational view of a medical apparatus inserted through a body cavity wall which incorporates the features of the present invention therein, with the body cavity wall shown in cross-section for clarity of description;

FIG. 2 is an enlarged end elevational view of the medical apparatus taken along line 2-2 of FIG. 1, with the trocar and body cavity wall shown removed for clarity of description;

FIG 3. is a reduced fragmentary side elevational view of the medical apparatus taken along line 3-3 of FIG. 2;

FIG 4. is an enlarged cross sectional view of the medical apparatus of FIG. 1, with the guide member shown in a first position and the sealing members shown in a first orientation;

FIG. 5 is an enlarged cross sectional view of the medical apparatus of FIG. 1, with the guide member shown in a second position and the sealing members shown in a second orientation;

FIG. 6 is a view similar to FIG. 2, however the medical apparatus is shown reduced, and the sealing members are shown in the second orientation;

FIG. 7 is a fragmentary side elevational view of the medical apparatus taken along line 7-7 of FIG. 6;

FIG. 8 is a fragmentary side elevational view of a medical apparatus similar to the one shown in FIG. 1, but this medical apparatus includes a strippable liner thereon (the handles are shown removed for clarity of description);

FIG. 9 is a fragmentary side elevational view of the medical apparatus shown in FIG. 8, with the strippable liner peeled off, and the sleeve peeled down and attached to an exterior surface of a body cavity wall.

Detailed Description of the Preferred Embodiment

While the invention is susceptible to various modifications and alternative forms, a specific embodiment thereof has been shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that there is no intent to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

Referring to FIGS. 1, 4 and 5 there is shown a medical apparatus 10 of the present invention advanced through an opening 26 in a wall 28 of a body cavity 34. The medical apparatus 10 includes a sleeve 18 having a passageway 24 extending therethrough. The sleeve 18 includes a number of sealing members 20. The medical apparatus further includes an actuator 38 and a trocar assembly 12. The actuator 38 includes a guide member 40 and handles 42. The sealing members 20 extend from a distal end 22 of sleeve 18. The trocar assembly 12 includes a cannula 14 and a trocar 16 positioned within passageway 24 of the sleeve 18.

As illustrated in FIG. 2, cannula 14, sealing members 20, and guide member 40 are all respectively nested within each other in a substantially concentric relationship (a portion of handles 42 is also shown extending above guide member 40). Cannula 14 is slidably fit into passageway 24 of sleeve 18 so as to allow its movement relative to sleeve 18. It should also be understood that cannula 14 and sleeve 18 are fit in such a way as to form a substantially gas tight junction so that substantially no gas leakage occurs through this junction during

insufflation of the body cavity 34. The aforementioned gas tight junction may be formed using rubber gaskets or o-rings.

Guide member 40 is slidably mounted onto sleeve 18 so it can be moved between a first position as shown in FIG. 4 and a second position as shown in FIG. 5. The double headed arrow 93 of FIG. 1 shows the direction of movement of guide member 40. Specifically, FIGS. 1 - 4 show guide member 40 placed in the first position, whereas FIGS. 5 and 7 show guide member 40 placed in the second position. As illustrated in FIGS. 1, 3, 5 and 7, the position of guide member 40 controls the movement of sealing members 20 between a first orientation and a second orientation. The sealing members 20 are positioned in the first orientation when the sealing members 20 are positioned in a substantially parallel relationship with passageway 24 of sleeve 18, as shown in FIGS. 1-4. The sealing members 20 are positioned in the second orientation when the sealing members 20 are positioned in a substantially orthogonal relationship with passageway 24 of sleeve 18 as shown in FIGS. 5 - 7. Moreover, as depicted in FIG. 6, when sealing members 20 are in the second orientation they extend from the distal end 22 of sleeve 18 (not shown in FIG. 6) so as to overlap one another, thereby completely surrounding passageway 24 of sleeve 18.

FIG. 6 shows sealing members 20 extending to form an annular flange. However, it should be appreciated that the present invention is not limited to the geometric shape formed by the extending sealing members. For example, other geometric shapes are contemplated, such as square or oval shaped configurations. Moreover, a single sealing member extending from a distal end of a sleeve, or a number of non-overlapping sealing members spaced around a

distal end of a sleeve are also contemplated. Furthermore, sealing members having perforations thereon which can be torn and separated prior to positioning in contact with the interior surface of a body cavity wall are also contemplated.

Sleeve 18 and guide member 40 can be made from any plastic material which is conventionally used in the medical device arts. Such material would be compatible with insertion into a body cavity. It should also be noted that the guide member used in the present invention can be manufactured to a size which only adds a minimal amount of bulk to the diameter of a trocar assembly. By doing so, trauma to the body cavity wall upon insertion of the medical apparatus of the present invention will be reduced.

Sleeve 18 and sealing members 20 are formed such that when no force is applied to sealing members 20 they spontaneously assume their second orientation (see FIGS. 5 - 7). Moreover, sealing members 20 are flexibly attached to distal end 22 such that when force is applied (i.e. the force applied by sliding guide member 40 over the sealing members 20) the sealing members 20 assume their first orientation (see FIGS. 1 - 4).

Handles 42 can be made of any material having the appropriate beam strength to move guide member 40 from the first position to the second position.

When performing a medical procedure with medical apparatus 10, such as a laparoscopic surgery, guide member 40 is placed into the first position (see FIGS. 1 - 4) so that sealing members are maintained in their first orientation (see FIGS. 1 - 4). Trocar 16 of medical apparatus 10 then contacts with and is advanced through wall 28 of a body cavity 34 to create an opening 26. Preferably, sleeve 18 and trocar 16 are simultaneously advanced through the opening 26 and into body cavity 34. It should be appreciated that maintaining

sealing members 20 in their first orientation facilitates the advancement of sleeve 18 through opening 26 and into body cavity 34.

Once distal end 22 of medical apparatus 10 enters into body cavity 34 through opening 26, handles 42 are moved away from opening 26 in the direction of arrow 94 (see FIG. 1) so as to slide guide member 40 to the second position (see FIGS. 5 and 7), thereby allowing sealing members 20 to assume their second orientation. Once sealing members 20 have assumed their second orientation they are positioned to contact the interior surface 56 of the body cavity wall 28 so as to prevent fluid communication between an area inside of the body cavity and an area outside of the body cavity through the space 36 defined between the opening 26 and the sleeve 18.

It should be understood that a ridge (not shown) or a number of "flange teeth" (not shown) extending from the surface of the sealing members and contacting the interior surface of the body cavity wall is also contemplated. Such a ridge or "flange teeth" will also contact the interior surface of the body cavity wall and assist in preventing fluid communication between the area inside of the body cavity and the area outside of the body cavity through the space defined between the opening and the sleeve. The aforementioned ridge or "flange teeth" will also keep the sealing members stationary relative to the interior surface of the body cavity during manipulations of the cannula.

Once the medical procedure is completed, handles 42 are moved toward opening 26 in a direction opposite to arrow 94 so as to slide guide member 40 to the first position (see FIGS. 1 - 4). The movement of guide member 40 to the first position forces sealing members 20 to assume their first orientation (see

FIGS. 1 - 4), thereby facilitating the removal of medical apparatus 10 from opening 26.

Now referring to FIG. 8, there is shown a medical apparatus 62 similar to the medical apparatus 10 shown in FIG. 1. Medical apparatus 62 is shown advanced through an opening 70 in a wall 66 of a body cavity 74. The medical apparatus 62 includes a sleeve 82 having a plurality of perforations 46 defined in its proximal end portion and an adhesive material disposed on its outer surface 91. The sleeve 82 includes a number of sealing members 64 positioned in a second orientation extending from distal end 78. The medical apparatus 62 further includes a guide member 72 positioned in the second position. Medical apparatus 62 also includes a strippable liner 84, surrounding and in contact with, the adhesive material disposed on outer surface 91. The strippable liner has perforations 86 formed thereon.

Medical apparatus 62 is used in the same manner as described above with reference to medical device 10. However, once the sealing members are positioned in contact with an interior surface 68 of body cavity wall 66, strippable liner 84 is torn along perforations 86 to expose the adhesive material disposed on the outer surface 91 of sleeve 82. As shown in FIG. 9, sleeve 82 is then torn along perforations 46 down to guide member 72 to form a number of elongated strips 88 having a first surface 95 with the adhesive disposed thereon. It is also contemplated that sleeve 82 may be formed from a material having the physical property of molecular orientation whereby a tear in the material runs readily only in a longitudinal direction along the length of sleeve 82. A sleeve formed from such a material will eliminate the need for the above described perforations.

Once the elongated strips 88 are formed, a first surface 95 of each strip 88 is attached to an exterior surface 90 of body cavity wall 66 with the adhesive.

An important aspect of using elongated strips 88 in the above described manner is that they cooperate with sealing members 64 to stabilize the position of medical apparatus 62 in opening 70. The attachment of elongated strips 88 to the exterior surface 90 of body cavity wall 66 also keeps sealing members 64 in contact with interior surface 68. This ensures that no fluid communication exists between an area inside of the body cavity 74 and an area outside the body cavity through the space 97 defined between the opening 70 and the sleeve 82.

Based upon the above description it will be understood by those skilled in the art that the present invention provides a medical apparatus for protecting a port site wound which adds only a minimal amount of bulk to the diameter of a trocar assembly. Moreover, it will be understood by those skilled in the art that the medical apparatus of the present invention can be retrofit to existing trocar assembly technology. Furthermore, the medical apparatus of the present invention allows minimally invasive surgical techniques, such as laparoscopic surgery, to be safely applied to cancer surgery.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description is to be considered as exemplary and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected. For example, while the mechanism described above for moving the sealing members from the first orientation to the second orientation has many benefits, other mechanisms may be used. One such mechanism may utilize

pressure in the body cavity to force the sealing members against the interior surface thereof.

What is claimed is:

1. A medical apparatus, comprising:

a trocar assembly including a cannula and a trocar; and

a sleeve having a number of sealing members extending therefrom and a passageway extending therethrough, said trocar assembly being positioned within said passageway of said sleeve.

2. The medical apparatus of claim 1, wherein said sleeve has a distal end and said sealing members extend therefrom.

3. The medical apparatus of claim 1, wherein:

said sleeve is positionable within an opening defined in a wall of a body cavity, and

said sealing members are movable between (1) a first orientation in which said sealing members are positioned to facilitate advancement of said sleeve into the opening, and (2) a second orientation in which said sealing members are positioned to prevent fluid communication between an area inside of the body cavity and an area outside of the body cavity through a space defined between the opening of the body cavity and said sleeve.

4. The medical apparatus of claim 3, further comprising:

an actuator for controlling movement of said sealing members between the first orientation and the second orientation.

5. The medical apparatus of claim 4, wherein said actuator includes a guide member positionable at (1) a first position in which the sealing members are maintained in the first orientation, and (2) a second position in which the sealing members are allowed to assume the second orientation.

6. The medical apparatus of claim 5, wherein the actuator further includes a handle connected to said guide member.

7. The medical apparatus of claim 3, wherein said sealing members partially overlap one another when said sealing members are positioned in the second orientation whereby fluid leakage between adjacent sealing members is prevented.

8. The medical apparatus of claim 1, wherein said sleeve has a plurality of perforations defined in a proximal end portion thereof.

9. The medical apparatus of claim 8, wherein said proximal end portion has an adhesive material disposed thereon.

10. A medical apparatus, comprising:

a sleeve having a number of sealing members attached to a distal end thereof and a passageway extending therethrough, and

a cannula positioned within the passageway of said sleeve, said cannula defining a lumen through which medical instruments may be advanced.

11. An apparatus for use with a trocar assembly, comprising:

a sleeve having a number of sealing members connected thereto and a passageway extending therethrough, said sealing members being movable between (1) a first orientation in which said sealing members are positioned to facilitate advancement of said sleeve into an opening defined in a wall of a body cavity, and (2) a second orientation in which said sealing members are positioned to prevent fluid communication between an area inside of the body cavity and an area outside of the body cavity through a space defined between the opening in the wall of the body cavity and said sleeve; and

an actuator for moving said sealing members between the first orientation and the second orientation.

12. The apparatus of claim 11, wherein said sleeve has a distal end and said sealing members are connected thereto.

13. The apparatus of claim 11, wherein said actuator further includes a handle connected to said guide member.

14. The apparatus of claim 11, wherein said sealing members partially overlap one another when said sealing members are positioned in the second orientation whereby fluid leakage between adjacent sealing members is prevented.

15. The apparatus of claim 11, wherein sleeve has a plurality of perforations defined in a proximal end portion thereof.

16. The apparatus of claim 15, wherein said proximal end portion has an adhesive material disposed thereon.

17. A medical procedure, comprising the steps of:

creating an opening in a wall of a body cavity;

advancing a medical apparatus through the opening and into the body cavity, said medical apparatus including (1) a sleeve having a number of sealing members connected thereto and a passageway extending therethrough, and (2) a trocar assembly positioned within the passageway of said sleeve. said trocar assembly including a cannula and a trocar; and

positioning said sealing members to contact an interior surface of said body cavity.

18. The medical procedure of claim 17, wherein said sleeve has a distal end and said sealing members are connected thereto.

19. The medical procedure of claim 17, wherein said advancing step includes the step of simultaneously advancing said sleeve and said trocar assembly through the opening and into the body cavity.

20. The medical procedure of claim 17, wherein said advancing step includes the step of maintaining said sealing members at a first orientation which facilitates advancement of the sleeve through the opening and into the body cavity.

21. The medical procedure of claim 20, wherein:

said positioning step includes the step of moving the sealing members from the first orientation to a second orientation, and

when said sealing members are positioned at the second orientation, said sealing members are positioned to prevent fluid communication between an area inside of the body cavity and an area outside of the body cavity through the space defined between the opening of the body cavity and the sleeve.

22. The medical procedure of claim 21, wherein:

said advancing step further includes the step of positioning a guide member at a first position so that said sealing members are maintained in the first orientation; and

said positioning step further includes the step of moving the guide member from the first position to a second position so that the sealing members are allowed to assume the second orientation.

23. The medical procedure of claim 17, wherein said creating step includes the step of creating the opening in the wall of the body cavity with said trocar.

24. The medical procedure of claim 17, wherein said sleeve has a plurality of perforations defined in a proximal end portion thereof, and further comprising the steps of:

tearing said sleeve along the perforations so as to form a number of elongated strips; and

attaching the elongated strips to an exterior surface of the wall of the body cavity.

25. The medical procedure of claim 24, wherein:

said proximal end portion has an adhesive material disposed thereon, and

said attaching step includes the step of attaching the elongated strips to an exterior surface of the wall of the body cavity with said adhesive material.

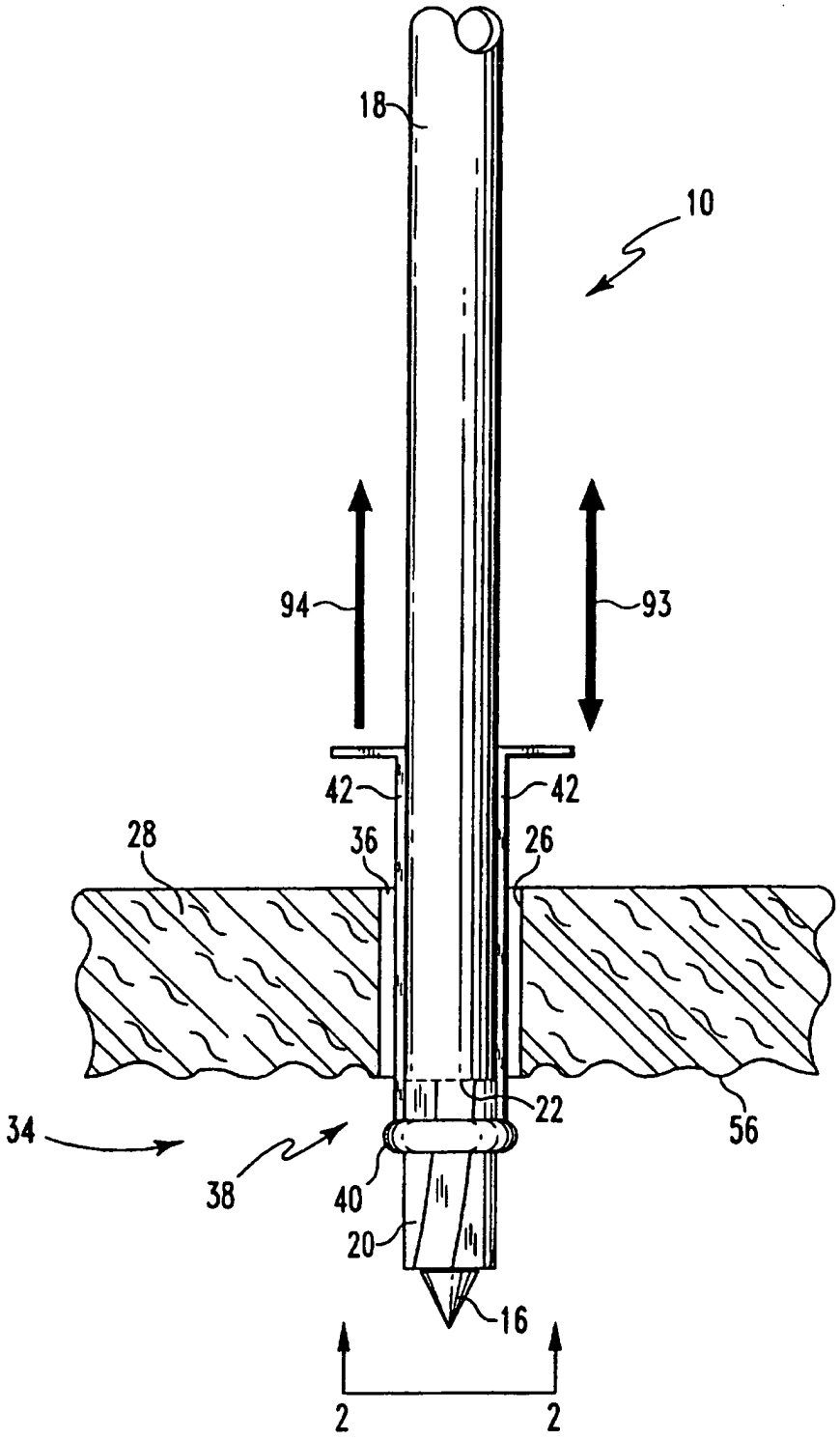

Fig. 1

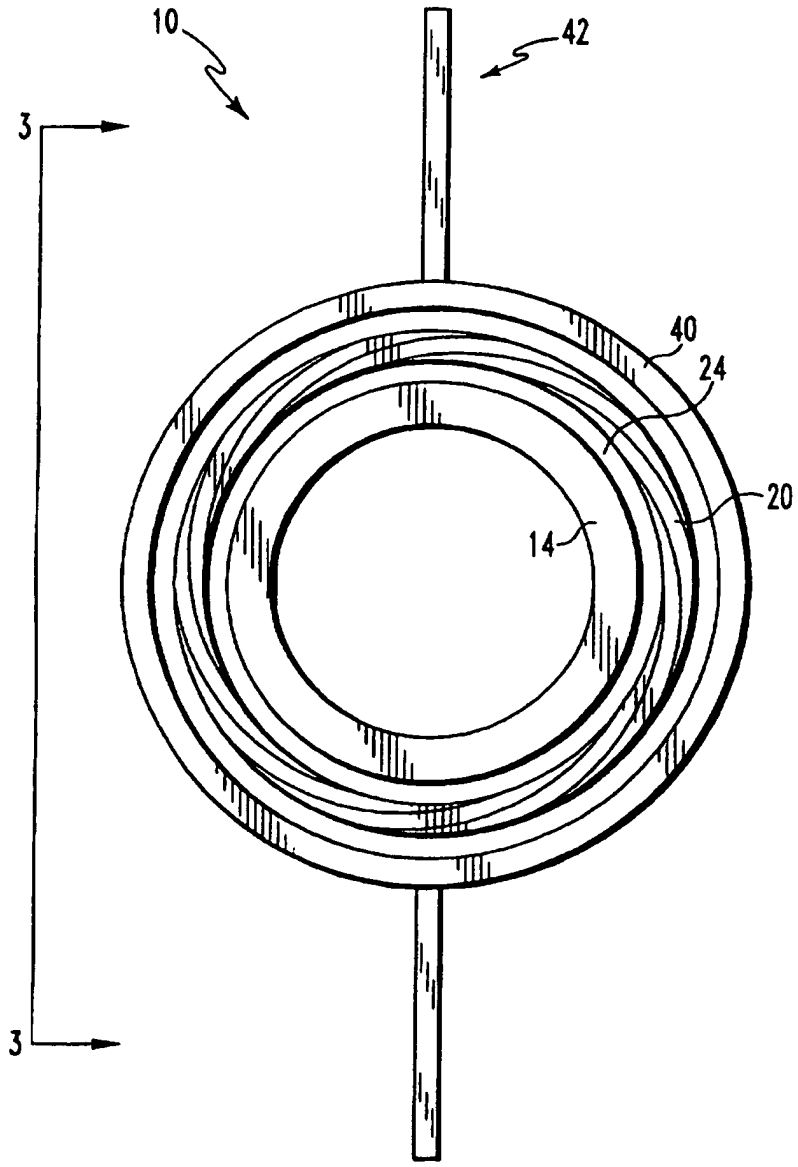

Fig. 2

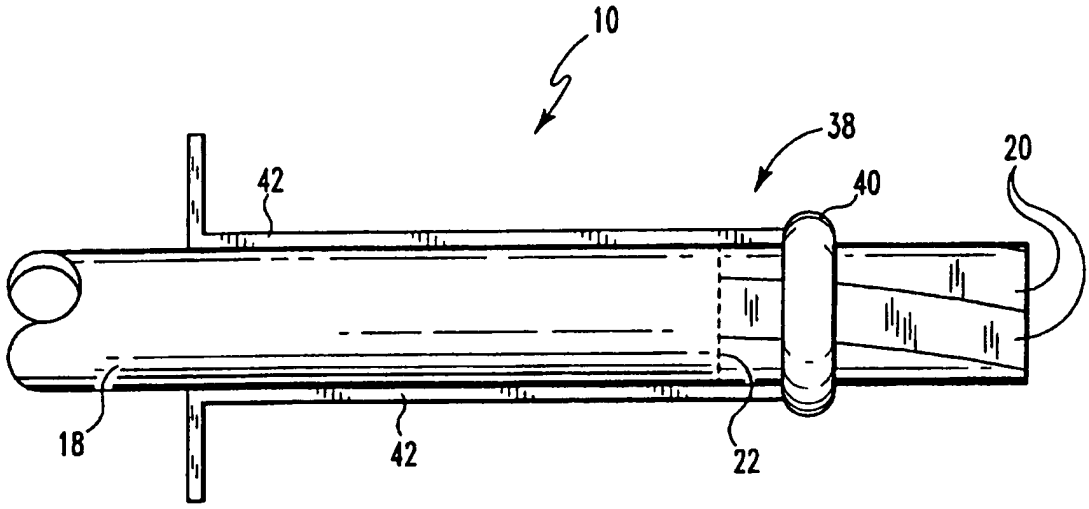
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Fig. 3

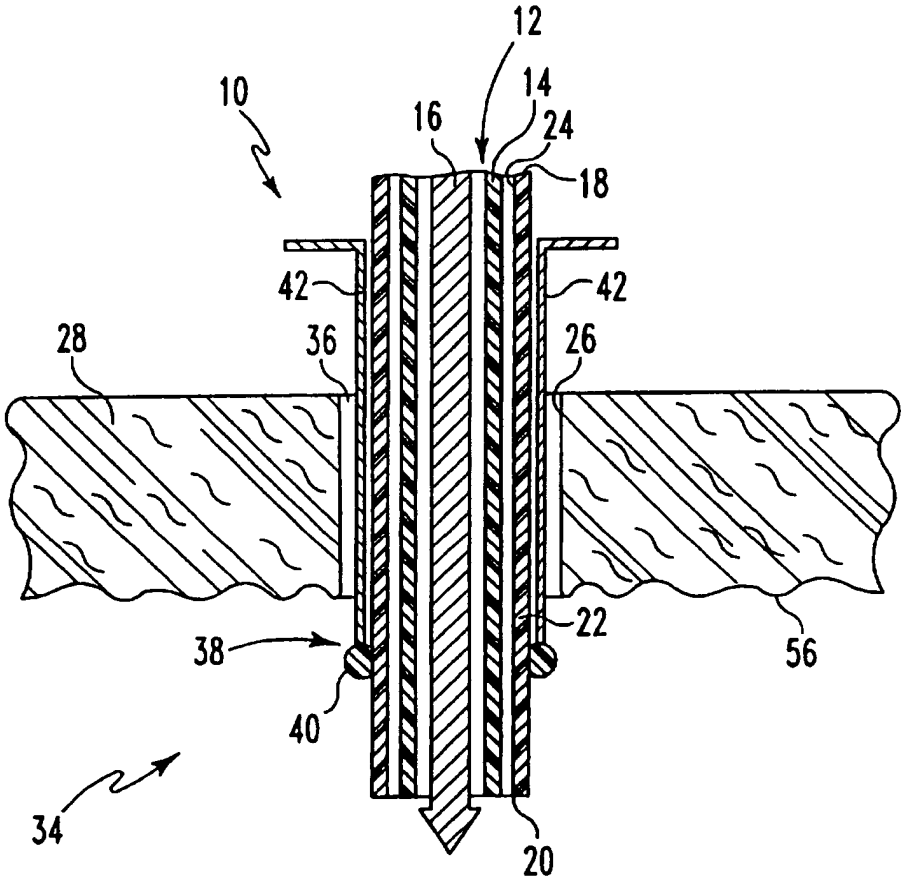
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Fig. 4

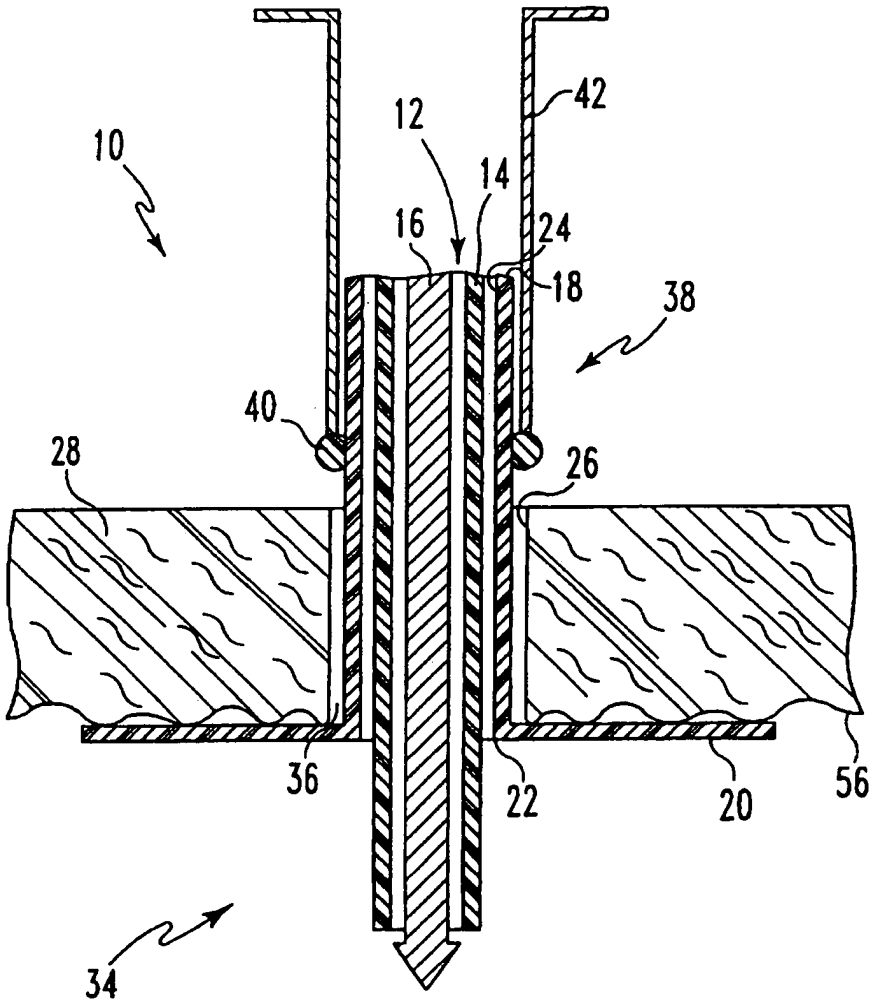

Fig. 5

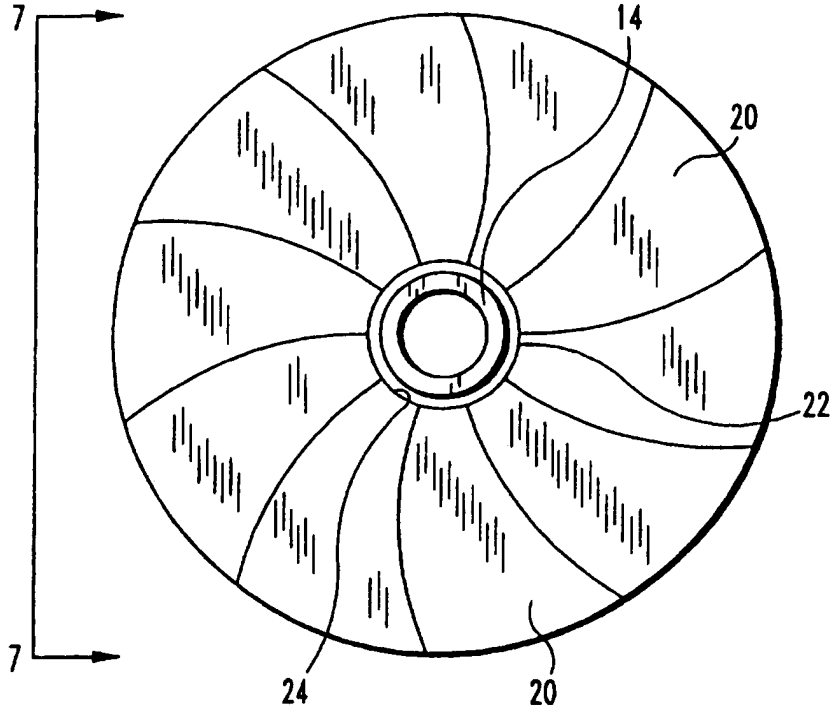

Fig. 6

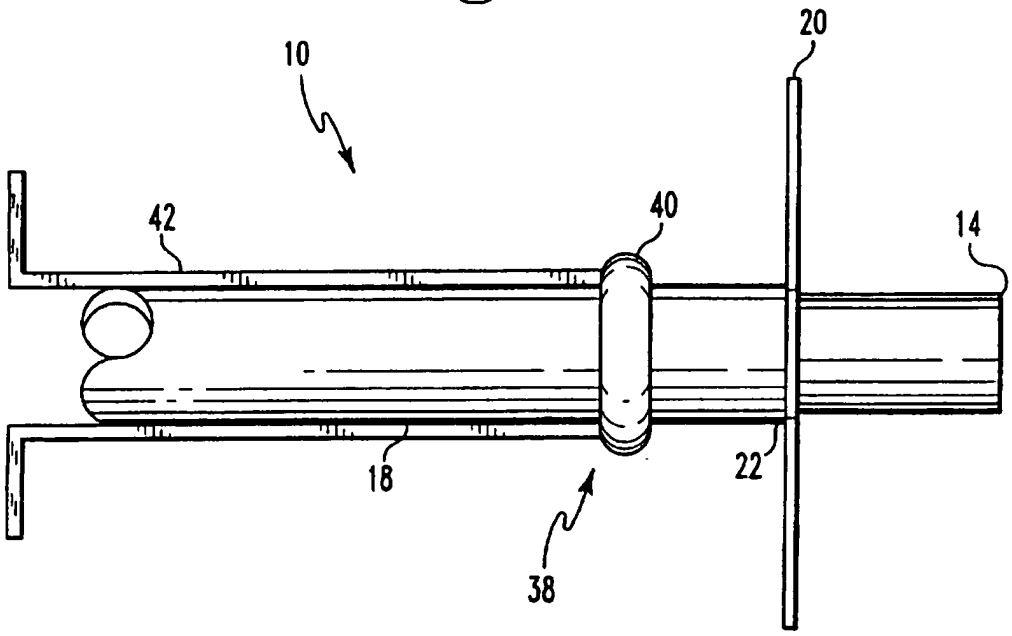

Fig. 7

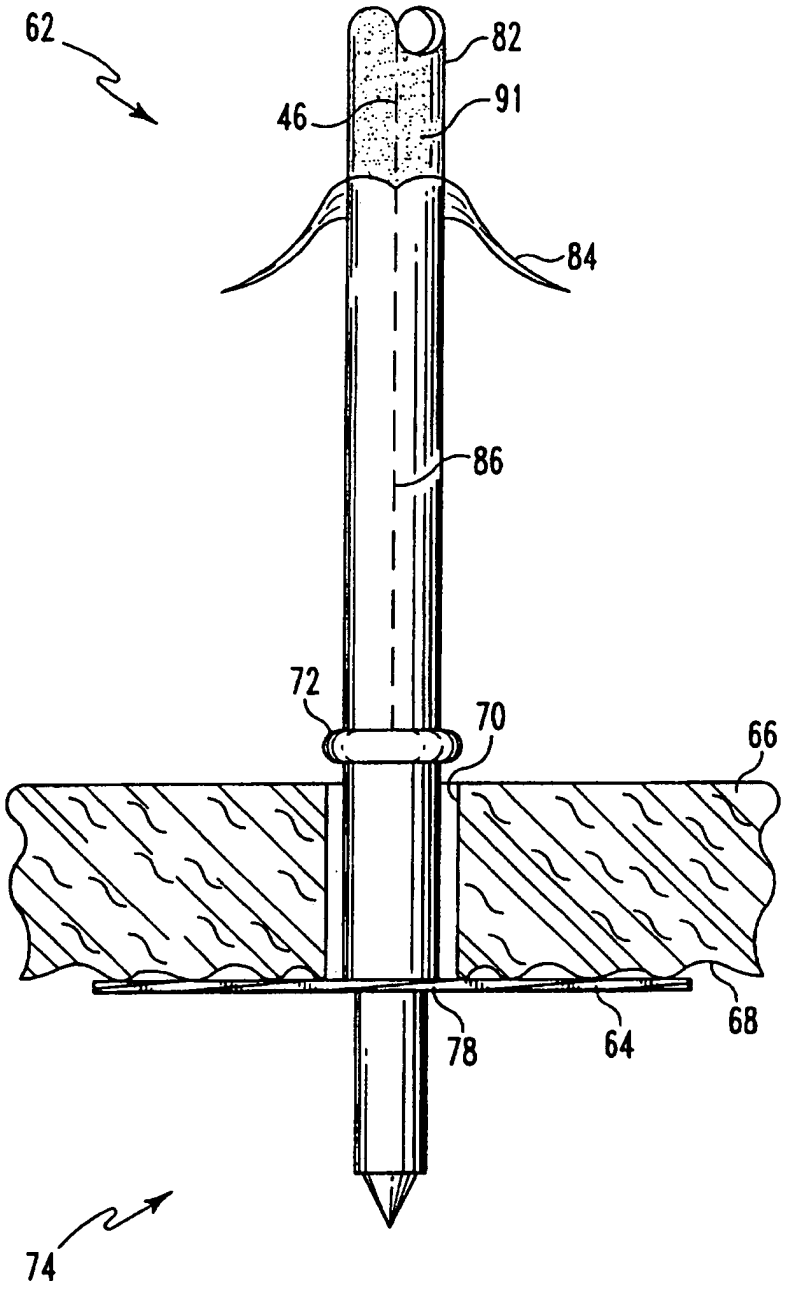

Fig. 8

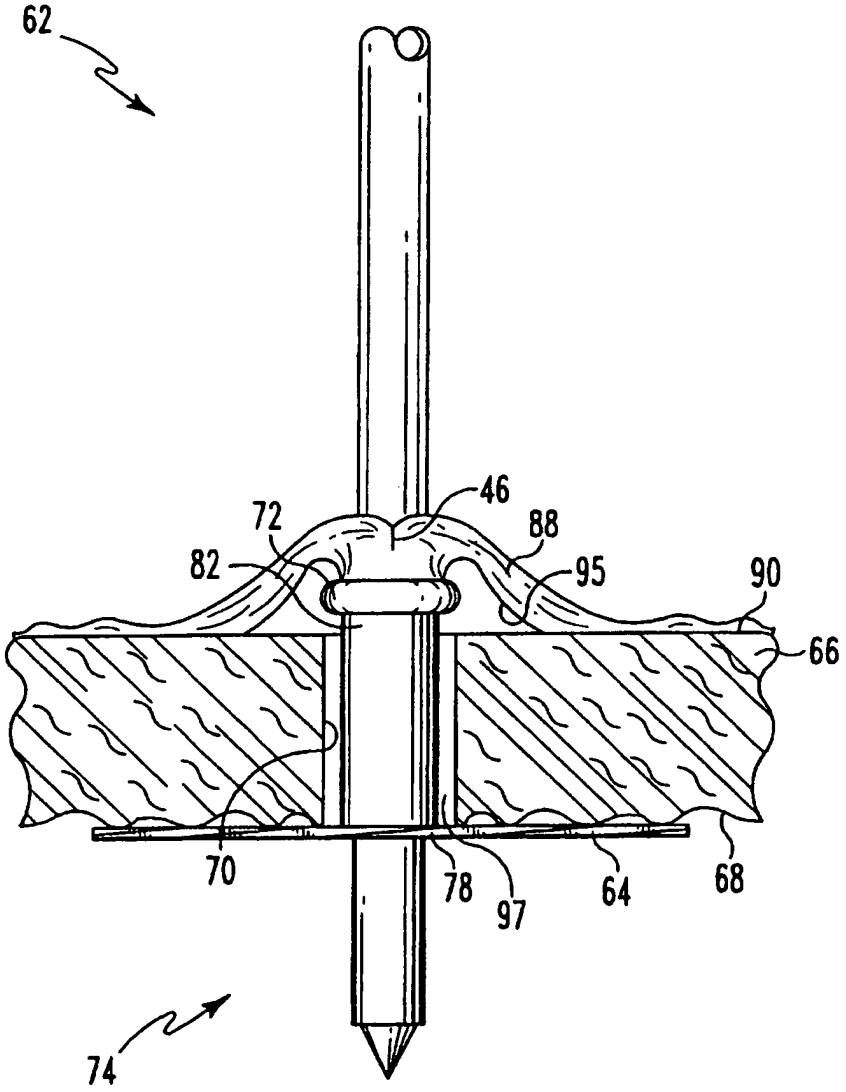

Fig. 9

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/US 97/02818

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 542 428 A (DEXIDE INC) 19 May 1993 see column 1, line 55 - column 2, line 16 see column 6, line 17 - line 20 see figures 1,2,18,19	1-4, 10-13
A	---	5-7,14
X	US 5 368 545 A (SCHALLER GUENTER ET AL) 29 November 1994 see column 2, line 24 - line 54 see column 3, line 30 - line 38 see figures 1,2,5	1,10,11
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
28 May 1997	06.06.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Chabus, H

Form PCT ISA 210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte. nal Application No
PCT/US 97/02818

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 370 647 A (GRABER JOHN N ET AL) 6 December 1994 see column 1, line 60 - line 65 see column 6, line 45 - line 60 see column 7, line 36 - line 43 see column 8, line 4 - line 16 see figures 4-17	1-7, 10-14
A	WO 95 24864 A (ADVANCED SURGICAL INC) 21 September 1995 see page 2, line 5 - line 14 see page 4, line 21 - page 5, line 8 see page 7, line 15 - line 17 see figures 1,2A-4B	1,10,11
A	EP 0 577 400 A (ETHICON INC) 5 January 1994 see column 2, line 36 - line 49 see column 9, line 48 - column 10, line 13 see column 11, line 16 - line 28 see figures 17-28	8,9,15, 16

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

I ational application No.	PCT/US 97/02818

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-25
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv) Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant s protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte nal Application No
PCT/US 97/02818

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0542428 A	19-05-93	CA 2080161 A	09-01-93
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(74) Agents: GERSHON, Neil, D. et al.; United States Surgical Corporation, Legal Dept., 150 Glover Avenue, Norwalk, CT 06856 (US).

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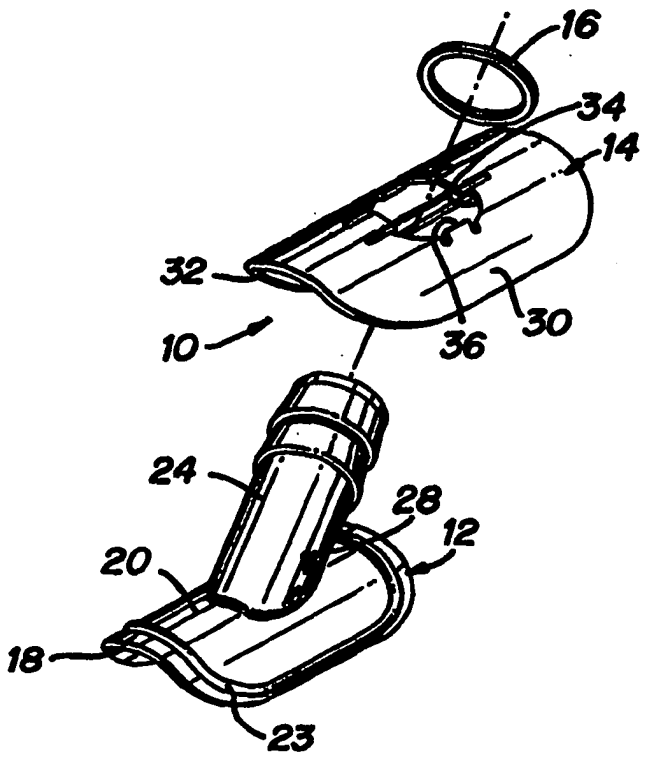
(54) Title: GRAFT ATTACHMENT ASSEMBLY

(57) Abstract

A graft attachment assembly that may be easily and quickly assembled is provided. The graft attachment assembly includes an attachment member including a base portion having a convex top surface and a branch portion having a passageway therethrough. The branch portion projects outwardly from the base portion. A clamp member having a concave bottom surface is configured to sealingly engage the top surface of the base portion and an opening is dimensioned to slidably receive the branch portion. The clamp member is slidable about the branch portion to a position adjacent the base portion to clamp tissue therebetween. A locking member is slidable about the branch portion and dimensioned to secure a vessel thereabout.



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GRAFT ATTACHMENT ASSEMBLY

BACKGROUND

1. Technical Field

The present disclosure relates generally to grafts for surgical use and, more specifically, to a graft attachment assembly which may be easily and quickly assembled. The graft attachment assembly is particularly suited for vascular bypass surgical procedures.

2. Background of Related Art

Vascular grafts for use in surgical procedures for bypassing a section of a main artery to prepare the bypassed section of artery for surgical repair are well known and have taken a variety of different forms. Typically, vascular grafts include an inlet conduit to receive blood flow from an arterial source and an outlet conduit to deliver blood flow to a downstream location, e.g., same or different arteries, body organs, etc. A sealing device is positioned adjacent to each inlet and outlet conduit. Because of the nature of bypass procedures, it is important that a vascular graft be implantable in a relatively short period of time and that the vascular graft be properly attached to the vessels and adequately sealed at its inlet and outlet ends.

U.S. Patent No. 4,712,551 to Rayhanabad discloses a vascular shunt having a tubular inlet conduit and a plurality of outlet branch portions. The inlet conduit is configured to be received within an upstream arterial lumen and includes a sealing mechanism in the form of an expandable collar. Each outlet branch portion is configured to be received within a downstream arterial lumen and also includes an expandable collar. An air supply source communicates with each collar via an air supply line to inflate the collar and move the inlet conduit and each of the outlet branch portions into sealing engagement with the inner walls of the arterial lumen. Although

the expandable seals are effective, the additional attachments required in the limited confines of a surgical site are undesirable.

U.S. Patent No. 5,156,619 to Ehrenfeld also discloses a vascular graft having a straight portion, and a flange portion including a crotch region. The flange portion is in the shape of a continuous flow curve and includes a suturing surface. The vascular graft is anastomosized to the aorta using hand applied sutures. Ehrenfeld's vascular graft still requires the time consuming and often times difficult process of suturing.

Accordingly, a need exists for an improved vascular graft that can be easily and quickly implanted, provides improved sealing, and can be easily and inexpensively manufactured.

SUMMARY

In accordance with the present disclosure, a graft attachment assembly is provided having an attachment member, a clamp member, and a locking member. The attachment member includes a base portion having a preferably concave top surface and at least one branch portion having a passageway therethrough projecting outwardly from the base portion. The clamp member is preferably formed with a convex bottom surface configured to sealingly engage the top surface of the base portion and has an opening dimensioned to slidably receive the branch portion. The clamp member is movable about the branch portion to a position adjacent the base portion to clamp tissue therebetween. The locking member, preferably a locking ring, is slidable about the branch portion and is dimensioned to secure a vessel thereabout. A sealing assembly, preferably in the form of a rib formed on one of the top and bottom surfaces and a channel aligned with the rib formed in the other of the top and bottom surfaces,

provides a seal between the base portion and the clamp member in the clamped position of the graft attachment assembly. The branch portion, illustratively, has at least one annular ramped surface positioned thereabout which is dimensioned to retain the locking ring in position about the distal end of the branch portion. In a preferred embodiment, the clamp member is formed with at least one flexible retaining member positioned about the opening and the branch portion is formed with at least one row of teeth which is aligned with the at least one retaining member in the clamped position to retain the clamp member in the clamped position adjacent the base portion. The retaining member is selectively movable into engagement with any one of the teeth in the row of teeth to accommodate tissues of different thicknesses. Advantageously, a branch portion of the graft attachment assembly may be attached directly to a body vessel and thus serve as a graft or, the branch portion may be attached to an intermediary graft and serve as an attachment member for a graft.

DETAILED DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view with parts separated of one embodiment of the vascular graft assembly;

FIG. 2 is a side partial cross-sectional view of the vascular graft assembly shown in FIG. 1 in an assembled condition;

FIG. 3 is a cross-sectional view taken along section line 3-3 of FIG. 2;

FIG. 4 is a perspective view of the vascular graft assembly shown in FIG. 1 implanted in the aorta; and

FIG. 5 is a perspective view of an alternate embodiment of the vascular graft assembly.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed graft attachment assembly will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

FIGS. 1 illustrates one embodiment of the presently disclosed graft attachment assembly shown generally as 10. Briefly, graft attachment assembly 10 includes an attachment member 12, a clamp member 14, and a locking member 16. Each member of the three part assembly is preferably molded from a biologically compatible material, such as polytetrafluroethylene, although other suitable methods and materials which meet the requisite requirements for a vascular graft, may also be used. The attachment assembly 10 is utilized to attach a vascular graft or a synthetic graft to a vessel without requiring sutures. Attachment assembly 10 may also be used to attach two body vessels.

Referring also to FIGS. 2 and 3, attachment member 12 is constructed with a base portion 18 having a convex top surface 20 configured to sealingly engage the interior wall of an arterial lumen. An annular rib 23 extends about the periphery of top surface 28. A tubular branch portion 24 defining a cylindrical passageway 21 extends outwardly from top surface 20 and is provided with at least one annular ramped surface 26 and at least one row of vertically aligned teeth 28. Illustratively, branch portion 24 is provided with two spaced annular ramped surfaces and four rows of vertically aligned teeth 28 spaced evenly about the periphery of branch portion 24,

although other configurations may be used. Locking member 16, which is preferably a locking ring, is dimensioned to be slidably received about tubular branch portion 24, and will be described in detail below.

Clamp member 14 has a body 30 having a concave bottom surface 32 configured to sealingly engage top surface 20 of base portion 18. An opening 34 dimensioned to receive tubular branch portion 24 of attachment member 12 is formed in body 30. A plurality of diametrically opposed flexible retaining members 36 define a portion of opening 34 and are positioned to engage rows of vertically aligned teeth 28 formed on the outer periphery of tubular branch portion 28. Preferably, a retaining member 36 is provided for each respective row of teeth 28. An annular channel 38 is formed in bottom surface 32 of clamp member 14 and is positioned to receive rib 23 of attachment member 12 when the clamp member 14 is fastened to base member 12 in a clamped position. Referring now to FIGS. 2-4, implantation of graft attachment assembly will now be described, by way of example, for use during a typical bypass procedure. An incision is made in aorta 40 and base portion 18 of attachment member 12 is inserted through the incision. Attachment member 12 is positioned such that branch portion 24 projects through the incision and top surface 20 of base portion 18 is in contact with the inner wall of aorta 40. Clamp member 14 is pressed downwardly onto attachment member 12 by sliding opening 34 of clamp member 14 about branch portion 24 to clamp tissue between bottom surface 32 of clamp member 14 and top surface 20 of base portion 18. Rib 23 forces tissue into channel 38 to provide a seal between clamp member 14 and attachment member 12. Clamp member 14 is retained in a clamped position by retaining members 36 which engage teeth 28. By providing multiple teeth in each row of teeth 28, the location of clamp member 14 with respect to base member 12 may be adjusted to accommodate tissues having different thicknesses.

After attachment member 12 is securely fastened to aorta 40, a vessel 44, e.g., the saphenous vein, may be fastened to branch portion 24 by positioning locking ring 16 about vessel 44, positioning vessel 44 about the distal end of branch portion 24, and sliding locking ring 16 about vessel 44 and branch portion 24 over the distal-most annular ramped surface 26 to a position between ramped surfaces 26. Locking ring 16 is constructed of a resilient material capable of passing over ramped surface 26 and compressing vessel 44 into sealing engagement with branch portion 24. Although branch portion 24 is shown oriented at a forty-five degree angle with respect to the longitudinal axis of attachment member 12, branch portion 24 may be oriented at any angle or direction suitable for the particular bypass application being performed. Moreover, since graft attachment assembly 10 is easily removable, it may be used for permanent or temporary applications.

FIG. 5 illustrates an alternate embodiment of the graft attachment assembly shown generally as 100. Graft attachment assembly 100 includes first, second, and third tubular branch portions 124a, 124b and 124c. Each branch portion has a pair of ramped surfaces 126 and at least one row of vertically aligned teeth 128a, 128b, and 128c. Clamp member 114 has three openings. Each opening is aligned with a respective branch portion and dimensioned to permit passage of the respective branch portion through the opening. Flexible retaining members 136a, 136b, and 136c define a portion of each opening and are engageable with the rows of teeth 128a-c to retain clamp member 114 in a clamped position fastened on attachment member 112. Although not illustrated, a locking member similar to locking ring 16 is associated with each branch portion 124a-c to sealingly fasten vasculature to the distal end of the respective branch portion.

It will be understood that various modifications may be made to the embodiments disclosed herein. As is apparent, any number of tubular branches can be provided to extend from graft member 12. Each branch can be placed at not only a 45° or 90° angle as shown, but can be placed at a variety of angles. Moreover, the tubular branches, on each graft member can be placed at different angles. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A graft attachment assembly comprising:

an attachment member including a base portion having a top surface and a branch portion having a passageway therethrough projecting outwardly from the top surface of the base portion; and

a clamp member having an opening configured to receive the branch portion, the clamp member being movable about the branch portion, wherein the bottom surface of the clamp member may be positioned adjacent to the top surface of the graft member to clamp tissue therebetween.

2. A graft attachment assembly according to claim 1, wherein the top surface of the base member is convex and the bottom surface of the clamp member is concave.

3. A graft attachment assembly according to any of the preceding claims, further including a sealing assembly between the top and bottom surfaces.

4. A graft attachment assembly according to any of the preceding claims, wherein the sealing assembly includes a rib formed on one of the top and bottom surfaces and a channel formed in the other of the top and bottom surfaces, the rib being aligned with the channel in a clamped position.

5. A graft attachment assembly according to any of the preceding claims, further comprising a locking ring dimensioned to be received about the branch portion to retain tissue thereabout.

6. A graft attachment assembly according to any of the preceding claims, wherein the branch portion includes at least one annular ramped surface positioned thereabout and the locking ring is flexible, the ramped surface being dimensioned to retain the locking ring in position about the branch portion.

7. A graft attachment assembly according to any of the preceding claims, wherein the clamp member includes at least one retaining member positioned about the opening and, the branch portion includes at least one tooth which is aligned with the at least one retaining member in a clamped position, wherein the retaining member is movable into engagement with the at least one tooth to retain the clamp member in the clamped position.

8. A graft attachment assembly according to any of the preceding claims, wherein the at least one tooth includes a plurality of teeth, the retaining member being selectively movable into engagement with any one of the teeth to accommodate tissues of different thicknesses.

9. A graft attachment assembly comprising:

a graft member including a base portion having a top surface and a branch portion having a passageway therethrough, the branch portion projecting outwardly from the base portion;

a clamp member having a bottom surface configured to sealingly engage the top surface of the base portion and an opening dimensioned to slidably receive the branch portion, the clamp member being movable about the branch portion to a position adjacent to the base portion to clamp tissue therebetween; and

a locking member slidable about the branch portion, the locking member being dimensioned to secure a vessel about the branch portion.

10. A graft attachment assembly according to any of the preceding claims, wherein the top surface of the base member is convex and the bottom surface of the clamp member is concave.

11. A graft attachment assembly according to any of the preceding claims, further including a sealing assembly between the top and bottom surfaces.

12. A graft attachment assembly according to any of the preceding claims, wherein the sealing assembly includes a rib formed on one of the top and bottom surfaces and a channel formed in the other of the top and bottom surfaces, the rib being aligned with the channel in the clamped position.

13. A graft attachment assembly according to any of the preceding claims, wherein the branch portion includes at least one annular ramped surface positioned thereabout, the ramped surface being dimensioned to retain the locking ring in position about the branch portion.

14. A graft attachment assembly according to any of the preceding claims, wherein the clamp member includes at least one retaining member positioned about the opening and, the branch portion includes at least tooth which is aligned with the at least one retaining member in the clamped position, wherein the retaining

member is movable into engagement with the at least one tooth to retain the clamp member in the clamped position.

15. A graft attachment assembly according to any of the preceding claims, wherein the at least one tooth includes a plurality of teeth, the retaining member being selectively movable into engagement with any one of the teeth to accommodate tissues of different thicknesses.

16. A graft attachment assembly according to any of the preceding claims, wherein the graft assembly is constructed from a biologically compatible material.

17. A graft attachment assembly according to any of the preceding claims, wherein the biologically compatible material is polytetrafluroethylene.

18. A method of attaching a graft to a first vessel comprising the steps of:

(a) placing a base portion of a graft attachment assembly within a lumen of the first vessel, the graft attachment assembly including a branch portion projecting from the base portion, the branch portion being positioned to extend from the vessel;

(b) positioning a second vessel about a first end of the branch portion; and

(c) frictionally securing the second vessel about the branch portion.

19. A method of attaching a graft to a first vessel according to any of the preceding claims, further comprising the step of clamping the base portion of the graft attachment assembly to the first vessel.

20. A method of attaching a graft to a first vessel according to any of the preceding claims, further comprising the step of locking the base portion of the graft attachment assembly in the clamped position with respect to the first vessel.

FIG_1

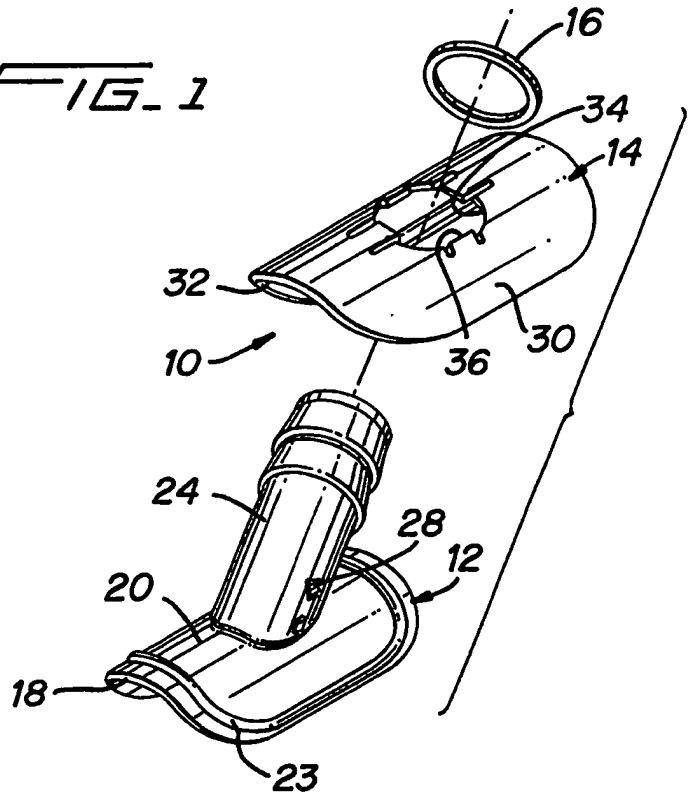
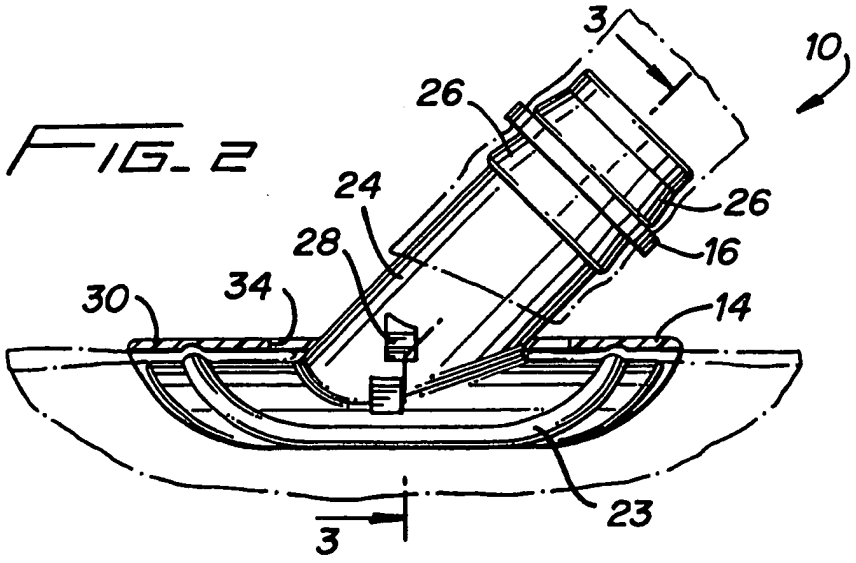


FIG_2



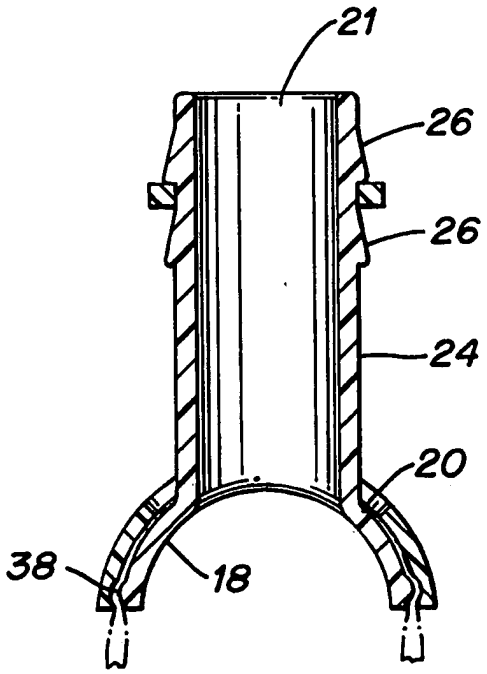


FIG_3

FIG. 4

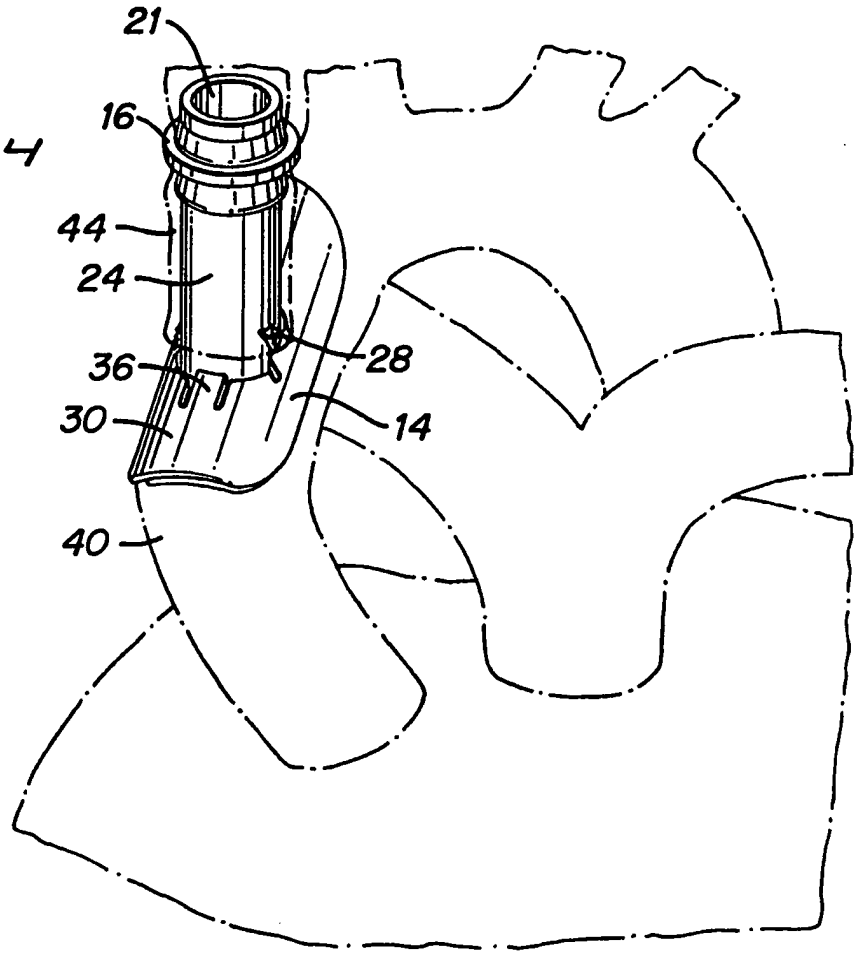

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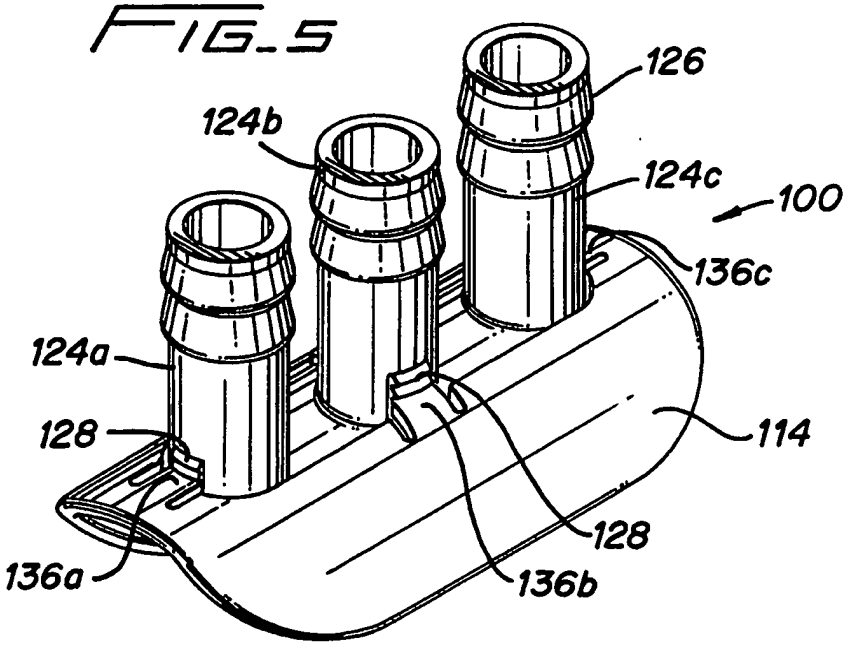
FIG. 5


126
124b
124c
100
136c
124a
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114
128
136a
136b

INTERNATIONAL SEARCH REPORT

Intern. ial Application No
PCT/US 98/05031

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 82 01644 A (KASTER) 27 May 1982 see abstract; figures	1,3,16 9
X A	FR 1 518 083 A (H. PFAU-WANFRIED GMBH) 17 July 1968 see page 2, right-hand column, line 37 - line 58; figures 2-4	1 9
A	WO 93 00868 A (OWEN) 21 January 1993	
A	US 4 523 592 A (DANIEL) 18 June 1985	

☐ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 July 1998	29.07.98
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Smith, C

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/05031

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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